Medical Instruments Technology Inc.

K012659

NOV 0 8 2001

Quality Reprocessing and Surgical Cost Containment Systems

Section 12: 510k Summary

Name of Submitter

Medical Instruments Technology, Inc.
385 North 3050 East
Saint George, UT 84790
Tel: (435) 674-4010
Fax: (435) 674-9819

Contact persons

Tom Haueter, RA/QA Manager
Crystal Batcabe, Assistant RA/QA Manager

Summary Prepared August 10, 2001

Device Name and Classification

Common Name: Trocar
Classification: Class II per 21 CFR 876.1500

Predicate Device

Ethicon Trocar (K971475)

Description of Device

MIT's reprocessed Trocars are composed of two main parts, an inner piece and an outer piece. The inner piece has a sharp blade and a spring-loaded shield or a blunt edge. The blade (or blunt edge) allows for insertion into the operative cavity. The shield provides for protection of internal organs from puncture once the operative cavity has been entered. The shield is automatically engaged when the operative cavity has been entered. The outer piece consists of a cannula with a gasket. The cannula allows for introduction of surgical instruments while the gasket assures pneumoperitoneum during the procedure.

Intended Use

The device is intended to establish a path for the introduction of minimally invasive instruments. Trocars, which are provided with a stopcock, are also intended to insufflate the operating area.

Technological Characteristics

MIT's reprocessed trocars have the same technological characteristics as the predicate devices. MIT does not change any of the design characteristics or materials during reprocessing. MIT has shown that the reprocessed trocars are substantially equivalent to the predicate devices by performance of the physical and functional tests. Additionally, we have tested the device for biocompatibility by performing the bioburden test and the ETO residual test. In all tests, the reprocessed devices have been equal the predicate devices

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 0 8 2001

Mr. Jack Speer
President
Medical Instruments Technology, Inc.
385 North 3050 East
Suite B
St. George, Utah 84790

Re: K012659
Trade Name: Dilating Tip Trocar
Regulation Number: 876.1500
Regulation Name: Laparoscope, General/Plastic Surgery
Regulatory Class: Class II
Product Code: GCJ
Dated: August 10, 2001
Received: August 13, 2001

Dear Mr. Speer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Walker MD

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

NOV 0 8 2001

510(k) Number (if known): K012659

Device Name: Cannulated Trocars

Indications For Use:

MIT's reprocessed trocars are indicated for use to establish a path of entry for minimally invasive instruments.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Walls

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K012659

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)